PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference AP102164	**FOR FURTHER ACTION**	See Form PCT/IPEA/416
International application No. PCT/FI2005/050028	International filing date *(day/month/year)* 11.02.2005	Priority date *(day/month/year)* 13.02.2004
International Patent Classification (IPC) or national classification and IPC INV. G01N21/64 G01N33/53		
Applicant ARCTIC DIAGNOSTICS OY et al.		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 6 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☐ *sent to the applicant and to the International Bureau)* a total of sheets, as follows:
      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
09.09.2005	22.05.2006
Name and mailing address of the international preliminary examining authority: European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized officer Seibert, J Telephone No. +31 70 340-4712

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/FI2005/050028

Box No. I Basis of the report

1. With regard to the **language**, this report is based on

   ☒ the international application in the language in which it was filed

   ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of:
   - ☐ international search (under Rules 12.3(a) and 23.1(b))
   - ☐ publication of the international application (under Rule 12.4(a))
   - ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

   Description, Pages

   1-36 as originally filed

   Claims, Numbers

   1-19 as originally filed

   Drawings, Sheets

   1/7-7/7 as originally filed

   ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

* *If item 4 applies, some or all of these sheets may be marked "superseded."*

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-12
	No:	Claims	13-19
Inventive step (IS)	Yes:	Claims	1-12
	No:	Claims	13-19
Industrial applicability (IA)	Yes:	Claims	1-19
	No:	Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1 Reference is made to the following documents:
D1: US-B1-6 342 397 (SOINI ERKKI ET AL) 29 January 2002 (2002-01-29)
D4: US-B1-6 344 653 (WEBB WATT W ET AL) 5 February 2002 (2002-02-05)
D5: US-A-5 815 262 (SCHROF ET AL) 29 September 1998 (1998-09-29)

2 Document D1, which is considered to represent the most relevant state of the art, discloses:
An in vitro diagnostic method for quantification of a clinical analyte from a clinical sample wherein the clinical analyte
undergoes a reaction or reactions with a reagent or reagents in one or several steps, or in a reaction sequence,
said reaction or reactions or reaction sequence resulting in a change of a measurable property of a compound or compounds cf said reaction or reactions or reaction sequence;
in which
i) said reactions or reaction sequence results in
- formation of a two-photon fluorescent compound, or
- a change in two-photon fluorescence properties of the reaction system comprising at least one two-photon fluorescent compound;

and
ii) said analyte is quantified by exciting said two-photon fluorescent compound or compounds and measuring two-photon exited fluorescence, and relating said measured fluorescence to method standardization data based on measurements obtained from reference material of said analyte,
from which the subject-matter of claim 1 differs in that
the clinical analyte is a clinical chemistry analyte.

2.1 The subject-matter of claim 1 is therefore new (Article 33(2) PCT).

2.2 The problem to be solved by the present invention may be regarded as enabling quantification of clinical chemistry analytes.

2.3 The solution to this problem proposed in claim 1 of the present application is

considered as involving an inventive step (Article 33(3) PCT) for the following reasons:
In document D1 a method for quantification of clinical analytes, in particular using bioaffinity assays, is disclosed. There is no mention of chemical reactions resulting in the formation of a two-photon fluorescent component or a change in the two-photon fluorescence properties of the reaction system.

3 The same reasoning applies, mutatis mutandis, to the subject-matter of the corresponding independent claim 8, which therefore is/are also considered not new/inventive.

4 The application does not meet the requirements of Article 6 PCT, because claim 13 is not clear.

4.1 Some of the features in the apparatus claim 13 relate to a method of using the apparatus rather than clearly defining the apparatus in terms of its technical features. The type of reaction taking place inside a suitable support of an apparatus cannot lead to a distinguishing feature of the apparatus. The intended limitations are therefore not clear from this claim, contrary to the requirements of Article 6 PCT.

5 Furthermore, the above-mentioned lack of clarity notwithstanding, the subject-matter of claim 13 is not new in the sense of Article 33(2) PCT, and therefore the criteria of Article 33(1) PCT are not met.

5.1 The document D4 (see Fig.1) discloses (the references in parentheses applying to this document):
A system *suitable* for in vitro diagnostic quantification of at least one clinical chemistry analyte from a clinical sample or samples, characterized in that the system comprises

a) a fluorometric device employing two-photon excited fluorescence (Fig.1) *suitable* for quantifying one or several clinical chemistry analytes, and
b) a data processing unit with software for dedicated data reduction *suitable* for said quantification of said analyte or analytes using said fluorometric device.

5.2 Similarly, document D5 (see Fig.1) deprives claim 13 of novelty.

6 Claims 2-7 and 9-12 are dependent on claims 1 and 8 respectively and as such also meet the requirements of the PCT with respect to novelty and inventive step.

7 Claims 14-19, dependent on claim 13, do not meet the requirements of the PCT with respect to novelty or inventive step.